

Office Action Summary

Application No.

09/084,441

Applicant(s)

LIN, J. T.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-106 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-106 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7,8
- 17) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other:

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Protests

It is noted that three protests have been filed in the instant application. The first protest filed November 19, 1999, has been returned to the protestor (see Office letter of February 7, 2000). This first protest contained ten references, and also included a protest of certain filing date issues. The protest was returned because the subject matter concerning the filing date issues was deemed inappropriate.

The second protest was filed January 24, 2000. This protest included 8 references, some of these references already cited in the first protest of November 19, 1999.

Finally, a third protest was filed on March 14, 2000. The third protest was a substantial copy of the first protest, with the subject matter concerning the filing date issue removed.

The rules regarding the entry and consideration of protests (MPEP Chapter 1900) are somewhat vague and unclear, particularly with respect to the filing of protests in reissue applications. In view of these vague guidelines, and in the interest of providing the most thorough possible examination of the application file, the second and third protests have been fully considered by the examiner. Additionally, most of the art cited in the second and third protests have been considered by the examiner as indicated on the PTO-1449 forms located in the file.

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It is noted that additional protests will be much more severely scrutinized before consideration. That is, any future protest must provide good and sufficient reason for such a late filing before it will be considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112: The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-38, 42, 50, 51, 59, 61, 62, 77 and 86 are rejected under 35

U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims recite a repetition rate of at least 20 hertz. The examiner maintains that there is no support for this limitation in the original specification.

Applicant asserts that the specification of the instant application discloses a repetition rate of 20-100Hz, and that parent application Serial No. 08/218,319 contains the same disclosure. However, the examiner maintains that there is a significant difference between "at least 20Hz", and "20-100Hz". In particular, the phrase "at least 20Hz" has no upper limit and includes a much wider range of values than the more limited (and disclosed) "20-100Hz".

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 24, 25, 27, 34, 37, 39, 42, 43, 46, 69, 71, 75-77, 82, 84, 86, 91 and 93 are rejected under 35 U.S.C. 102(b) as being anticipated by L'Esperance, Jr. ('608).

L'Esperance, Jr. discloses a laser system for removing tissue from the cornea. The laser includes a pulsed output which may be pulsed at 20-500 Hz (column 3, lines 20-22). Also, the laser output has an energy of less than 10 mJ/pulse (column 3, line 2). The laser beams are scanned onto a corneal surface using a computer scanner (figure 2), and tissue is removed by scanning successively larger diameters of tissue (column 5, lines 27-30). The scans inherently include an overlapping pattern as all tissue is removed, and L'Esperance, Jr provides a means to adjust the rate of increment (i.e. amount of overlapping) of each successive pass (column 6, lines 8-13).

L'Esperance, Jr. also discloses the use of infrared and ultraviolet (i.e. excimer) laser sources (column 2, line 67 through column 3, line 22).

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Claims 24, 27, 28, 31, 33, 36, 38-40, 42, 45, 47, 90-92, 94 and 106 are rejected under 35 U.S.C. 102(b) as being anticipated by the article to Ren et al ("Corneal Refractive Surgery... Solid State Laser").

The article to Ren et al discloses a laser system for removal of corneal tissue. The system includes a UV laser which operates at 213 nm (page 129). The output energy is less than 10 mJ (page 130), and the spot size was less than 1 mm in diameter (page 130). Approximately 0.3 micrometers of tissue were removed per pulse (page 130). Ren et al also teach that the solid state laser may be pulsed at a very high rate (i.e. KHz range), and teach of scanning the pulses onto corneal tissue. Figure 1 shows a linear, overlapping scan. Ren et al also teach that diode lasers may be used to generate the laser energy (page 129).

Claim 99 is rejected under 35 U.S.C. 102(e) as being anticipated by Parel et al ('759).

Parel et al disclose a laser system for performing photocoagulation on a corneal surface. The device includes an infrared laser source with a wavelength between 1.3 and 3.3 microns (column 5, lines 11-16).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 11-18, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over L'Esperance, Jr. ('608) in view of the teachings of Bille ('679) and the article to Ren et al.

As discussed previously, L'Esperance, Jr discloses a system and method of removing corneal tissue. The system includes an ultraviolet laser with an energy level which may be less than 10 mJ per pulse. The system further includes a focusing/scanning means including a computer to deliver the laser beam to tissue. The only features not expressly taught by L'Esperance, Jr. is the use of a galvanometer as the scanning mechanism, and the removal of from 0.05 to 0.5 microns of tissue per pulse.

Bille discloses a device for providing laser light to the cornea. In particular, Bille teaches that it is known to provide a galvanometer to scan the laser light to the cornea. To have provided a well known scanning mechanism, such as a galvanometer, to scan the laser light in the L'Esperance, Jr. system would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Bille.

With regard to the removal rate of tissue, Ren et al teach of a similar laser system for the removal of corneal tissue. In particular, Ren et al teach that the laser removes tissue in increments of approximately 0.3 microns per pulse. The laser and steps disclosed by Ren et al are similar to those of the L'Esperance, Jr. system. To

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have removed any reasonable amount of tissue per pulse would have been an obvious, if not inherent, feature of the L'Esperance, Jr system, particularly since Ren et al teach that a similar system and method removes a desired amount of tissue within the applicant's disclosed range.

Claims 5-10 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over L'Esperance, Jr. ('608), Bille ('679) and the article to Ren et al as applied to claims 1-4, 11-18, 22 and 23 above, and further in view of the teaching of Parel et al ('759).

The combination of the L'Esperance, Jr. system with the Bille and Ren et al teachings has been addressed. While L'Esperance, Jr. discloses that both UV and near infrared laser energy may be used, there is no disclosure of all the specific types of lasers which may be used to achieve these frequencies.

Parel et al disclose a laser system for providing laser light for the removal of corneal tissue. In particular, Parel et al disclose numerous types of laser for providing infrared wavelengths between 1.3 and 3.3 microns, as well as an Argon Fluoride laser emitting a wavelength of 193 nm. Among the laser disclosed by Parel et al are HF:YAG, Er:YAG, Ho:YAG and Nd:YAG. The pulse duration may be set to any reasonable time frame (i.e. through Q-switching) as is well known in the art. Further, Ren et al teach that such infrared lasers may be achieved using diodes (page 129).

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To have provided the L'Esperance, Jr. system, as modified by the teachings of Bille and Ren et al, with any well known laser source would have been an obvious design consideration for one of ordinary skill in the art, particularly since Parel et al teach that many laser sources may be readily substituted.

Claims 26, 30, 32, 35, 37, 38, 41, 44, 47, 70, 72 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over L'Esperance, Jr. ('608) in view of the teaching of Sumiya ('799).

The L'Esperance, Jr. system has been addressed previously. While L'Esperance, Jr discloses that the laser beam is scanned onto tissue using a computer, there are no specifics of the scanning procedures (i.e. randomized, synchronous, etc.). It is noted that L'Esperance, Jr teaches of the overlapping of laser pulses to create a smooth ablation, and that the scanning pattern may include concentric circles.

Sumiya disclose a corneal laser treatment device which utilizes a scanner to deliver laser energy to tissue. In particular, Sumiya teach that the scanner may be synchronously with the pulses (column 4, lines 64-68), and the pulses are overlapped to create a uniform level of ablation. The examiner maintains that using any desired degree of overlapping, and any particular pattern (e.g. linear, circular, etc.) would be within the purview of one of ordinary skill in the art. Randomized scans and pre-programmed scans would also be obvious to one of ordinary skill in the art, particularly in view of the use of computers to control the scanning (see L'Esperance, Jr.).

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To have provided the L'Esperance, Jr. system with any particular scanning pattern, including synchronous scanning, would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Sumiya.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over L'Esperance, Jr. ('608) and Sumiya ('799) as in the previous rejection, and further in view of the teaching of Ren et al.

The combination of L'Esperance, Jr. and Sumiya has been addressed above. Neither reference discloses the particular spot size for the laser beam.

The examiner maintains that the range of spot-sizes for laser beams in corneal surgery is generally well known in the art. To that end, Ren et al teach of providing a corneal laser with a spot-size of 0.2 mm in diameter.

To have provided the L'Esperance, Jr. system, as modified by the teaching of Sumiya, with any reasonable spot-size for the laser beam would have been an obvious consideration for one of ordinary skill in the art, particularly since Ren et al teach of the use of a small spot-size in a similar procedure.

Claims 28, 29, 31, 33, 36, 40, 45, 73, 74, 78-80, 85 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over L'Esperance, Jr. ('608) in view of the teaching of Ren et al.

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The L'Esperance, Jr. system has been addressed previously. L'Esperance, Jr fails to disclose the particular amount of tissue removed with each pulse, and the spot-size of the pulse.

Ren et al, as previously discussed, discloses a similar procedure and specifically teaches that the laser may be provided with a spot-size of 0.2 mm diameter, and the ablation rate is 0.3 microns per pulse.

To have provided the L'Esperance, Jr. system with any particular spot size or ablation rate would have been an obvious modification for one of ordinary skill in the art, particularly since Ren et al teaches that these parameters are used in the art.

Claim 81 is rejected under 35 U.S.C. 103(a) as being unpatentable over L'Esperance, Jr. ('608) and Ren et al as in the previous rejection, and further in view of the teaching of Bille ('679).

The combination of the L'Esperance, Jr. system with the teaching of Ren et al has been addressed above. While both L'Esperance, Jr and Ren et al disclose means to scan the laser beam, neither reference specifically disclose a galvanometer scanning means.

Bille et al teach that it is generally known to use a galvanometer to scan laser energy onto corneal tissue.

To have provided the L'Esperance, Jr system, as modified by the teaching of Ren et al, with a galvanometer to scan the laser energy onto corneal tissue would have

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been an obvious consideration for one of ordinary skill in the art in view of the teaching of Bille.

Claims 48-52, 55, 56, 60, 61 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over L'Esperance, Jr. ('608) in view of the teaching of Bille et al ('679).

The L'Esperance, Jr device, as addressed previously, fails to disclose a galvanometer to scan the laser energy onto the corneal tissue.

Bille et al teach that it is known to use a galvanometer to scan laser energy onto corneal tissue.

To have provided the L'Esperance, Jr system with a galvanometer to scan the laser energy onto corneal tissue would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Bille.

Claims 53, 54, 57-59, 62 and 64-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over L'Esperance, Jr ('608) and Bille ('679) as applied to claims 48-52, 55, 56, 60, 61 and 87 above, and further in view of the teaching of Ren et al.

Again, the combination of L'Esperance, Jr and Bille has been addressed. Ren et al disclose the particular beam spot size and rate of ablation (i.e. 0.3 microns per pulse) acceptable in a corneal ablation procedure.

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To have provided the L'Esperance, Jr system, as modified by the teaching of Bille, with any reasonable spot-size or rate of ablation would have been an obvious consideration for one of ordinary skill in the art, particularly in view of the teaching of Ren et al.

Claims 63 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over L'Esperance, Jr ('608) and Bille ('679) as applied to claims 48-52, 55, 56, 60, 61 and 87 above, and further in view of the teaching of Sumiya ('799).

The combination of L'Esperance, Jr. and Bille has been addressed.

Sumiya teaches that it is generally known to provide scanning of a laser beam synchronously with the laser pulses (bottom of column 4).

To have provided the L'Esperance, Jr system, as modified by the teaching of Bille, with a synchronous scanning means for providing the laser light to corneal tissue would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Sumiya.

Claims 100-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parel et al ('759) in view of the teaching of Ren et al.

Parel et al, as addressed previously, disclose a method of photocoagulation of tissue (column 5, lines 10-15) comprising the steps of providing an infrared laser beam with a wavelength between 1.3 and 3.3 microns, and scanning the beam on corneal

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tissue. While Parel et al disclose numerous types of solid-state lasers for achieving the desired wavelengths, there is no disclosure of using a diode to pump the lasers.

Ren et al also teach that it is known to use solid-state lasers to create a laser beam for treating corneal tissue. More particularly, Ren et al teach that diode lasers may be used to generate the desired wavelengths (see page 129).

To have used diode lasers in the Parel et al system to create the various wavelengths as set forth in applicant's claims would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Ren et al.

Claim 93 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ren et al in view of the teaching of L'Esperance, Jr ('608).

Ren et al disclose the method of performing corneal refractive surgery comprising selecting a laser with a pulsed output and an energy level less than 10 mJ per pulse, scanning the laser beam in an overlapping pattern onto the corneal surface, and removing 0.3 microns of tissue per pulse. Ren et al fails to disclose a pulsing frequency of greater than 50 Hz (although Ren et al teach that solid state lasers may be pulsed very rapidly).

L'Esperance, Jr disclose a very similar method, and further teach that it is known to pulse such a laser at between 20 and 500 Hz.

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To have provided the Ren et al system with a means to pulse the laser at greater than 50 Hz to treat tissue would have been an obvious modification for one of ordinary skill in the art in view of the teaching of L'Esperance, Jr.

Claim 105 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ren et al in view of the teaching of Bille ('679).

The Ren et al reference has been addressed. Ren et al fails to disclose the use of a galvanometer to scan the laser beam onto corneal tissue.

Bille teaches that it is known to use a galvanometer to scan laser energy onto corneal tissue.

To have provided the Ren et al system with a galvanometer to scan the laser energy onto corneal tissue would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Bille.

Response to Arguments

Applicant's arguments with respect to claims 1-106 have been considered but are moot in view of the new ground(s) of rejection.

In particular, applicant's arguments with respect to the Lin and Lai references not qualifying as prior art have been deemed persuasive. However, new grounds of rejection have been set forth accordingly.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on 9 hour.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda M Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Michael Peffley/mp
Primary Examiner
Art Unit 3739
March 29, 2000

Michael Peffley
MICHAEL PEFFLEY
PRIMARY EXAMINER
Av 3739

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